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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,442	03/07/2000	Gopinathan K. Menon	680.0035USU	1007
60723	7590	04/22/2008	EXAMINER	
AVON PRODUCTS, INC.			BARHAM, BETHANY P	
AVON PLACE				
SUFFERN, NY 10901				
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			04/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT.DEPARTMENT@AVON.COM

Office Action Summary	Application No. 09/521,442	Applicant(s) MENON, GOPINATHAN K.	
	Examiner Bethany Barham	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 36-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/13/08</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Summary

Notice the previous office action (mailed on 8/28/07 and resent on 3/19/08) has been **vacated**. The prior art rejection of record is hereby **withdrawn**.

Receipt of IDS filed on 03/13/08 is acknowledged. Receipt of IDS filed on 6/11/07 was previously acknowledged. Receipt of Applicant's Remarks filed on 06/01/2007 is also acknowledged. Claims 36-51 are pending. Claims 36-51 are rejected.

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/01/2007 has been entered.

Response to Arguments and Remarks **Rejections-35 USC § 112:**

Applicants have submitted substantial art and arguments, specifically US Patent # 6,852,343 B2, which not only teaches treating cellulite with an oil from a plant but also teaches that cellulite is connected to expression of PPAR, thereby rendering the 112 enablement rejection moot.

The Examiner would like to point out that 'ameliorating or treating cellulite' is being defined in this instance as the improvement of aesthetic appearance of cellulite. Since the prior art seems to be in conflict as to whether or not cellulite can actually be treated. Applicant submitted 3 clinical studies (all post filing date art) with their last response, and even those studies such as Rao et al in 2005, teach that cellulite has limited treatment options that are tolerable and effective, that there remains a poor understanding of the pathophysiology coupled with very few scientifically based studies, and that the degree to which any remedy is effective in cellulite clearance or reduction remains questionable (Rao et al, Summary and Intro.). Rao et al discloses several methods for evaluating cellulite with the 'observation' or visual method being the best and most relied upon and that various predisposing factors are known to contribute to cellulite, however in their study the only one that they kept constant was gender (as all subjects were female), which throws significant deviation into any results obtained (pg. 96-97, predisposing factors and evaluation). As such they discuss that there is no current cure or gold standard for the treatment of cellulite due in part to the minimal understanding of cellulite pathophysiology and poor therapeutic effectiveness of most treatment modalities (pg. 100, Management). They also acknowledge the various inherent flaws in their study that can lead to considerable error and deviation, but then conclude that they demonstrate a topical agent can be used to treat cellulite (pg. 101, present study).

Further, Bertin et al as submitted by applicant states that the events leading to the appearance of cellulite are still debated and most of the results with the product and

placebo were indistinguishable, except for the improvement of visual or aesthetic appearance and concluded that a measurable activity was observed for the active product (pg. 199, intro; pg. 205, results, and pg. 210, conclusion).

It is the Examiner's understanding from the art taught that there still seems to exist considerable debate as to the etiology of cellulite (also see cited as interest) and even post dated double-blind studies acknowledge this as well as the fact that treatment is not currently known.

CITED AS INTEREST

A review article "Cellulite: nature and aetiopathogenesis" by Terranova, F. et al (2006), which teaches that only a limited number of studies on cellulite have been published and that many have reached antithetical conclusions, that it is not yet possible to reconcile the extreme differences of opinion, and that three major and conflicting theories have emerged in relation to the ethiopathogenesis of cellulite (abstract). They also teach that numerous known methods and treatments for cellulite have only a fleeting moment of triumph before proving to be ineffective (pg. 158, Intro.). They conclude that since no studies have been published to prove or disprove theories of ethiopathogenesis of cellulite and no data available to clarify whether the recently identified functional properties of the adipose tissue are involved in pathogenesis and therefore there remains only theory and hypothesis (pg. 163, last paragraph).

Further, an Editorial "The Disease of Cellulite" by Zoe Diana Draelos (2005), teaches that the exact etiology of cellulite is unknown, but that several theories deserve mention (pg. 221, 3rd Paragraph). The author states that "trying to treat cellulite is much

like trying to ignore the normal female physiology that allows for the continuation of the species” (pg. 222, last Paragraph).

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. How to make the composition is not taught in the instant specification and further no correlation exists between *in vivo* and *in vitro*; the instant specification only provides written description for perilla oil used in treating cells. The results are not commensurate with the scope of the instant claims, as the specification teaches that perilla oil must be ‘aged’ or ‘stored’ prior to obtaining PPAR activity (pg. 6, lines 7-13). The art US 5,312,834 teaches a composition of perilla oil for treating the skin with this function that should have the same activity, but the instant specification teaches that it does not. As such the claims lack written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 36-51 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claim 36-51 fail to correspond in scope with that which applicant regard as the invention can be found in the specification filed 3/7/2000. In that paper, applicant has stated (pg. 6, lines 7-13) that “It is surprising and unexpected that perilla oil inhibits upregulation by PPAR agonists, as perilla oil itself contains PPAR agonists such as linolenic acid and linoleic acid. This may be attributable to perilla oil undergoing oxidation on storage due to the high content of unsaturated fatty acids. The oxidation process may alter the PPAR stimulating activity of linolenic acid and linoleic acid...”, and this statement indicates that the invention is different from what is defined in the claim(s) because the instant claims do not require that perilla oil is 'aged' or stored for a certain amount of time prior to application on the cellulite. The instant claims suggest instead that fresh perilla oil treats cellulite. This is not what the instant specification teaches and as such there is a failure to claim the invention.

Further, what are the ‘metes and bounds’ of “improve the aesthetic appearance thereof”? There exists no quantitative or measurable result of the ability of perilla oil to “improve the aesthetic appearance thereof”. As such the instant claims are indefinite as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,945,109 ('109) in view of US 5,312,834 ('834).

The limitations of claims 35-51 are taught:

- '109 teaches a cosmetic product for topical administration for cellulite (abstract).
'109 teaches that the cosmetic product comprises a topical application of an ointment, gel, cream, etc and that formulations include essential oils and plant extracts (col. 5, lines 31-54).
- '109 teaches that the product is topically applied once to twice daily (col. 6, lines 6-25).
- '109 example 1 teaches a groundnut oil added at 10% by weight to a cellulite cream.
- '109 does not teach perilla oil, but does teach essentials oils and plant extracts.
- '834 teaches that various creams and ointments for the skin contain chemicals that cause sever allergic reactions and can complicate skin problems (col. 1, lines 13-24 and col. 3, lines 17-28) and that a composition comprising perilla oil

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which has no side effects effectively treats skin and provides for good color and resilience of skin (col. 3, lines 41-47 and col. 5, lines 63-67). Examples teach that the perilla oil is from perilla seed of *Perilla frutescens* var. Further, '834 teaches that the 'aesthetic' appearance of skin is improved over time (Examples).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '109 in view of '834. One of ordinary skill in the art would have been motivated to combine the teachings of '109 and '834, since many people are known to have allergic reactions as taught by '834 and '834 teaches that perilla oil is safe and has no side effects. '109 teaches that the cream contains groundnut oil which many people are known to have severe allergies to. '109 teaches a topical cream for the treatment of cellulite that includes plant oils, while '834 teaches perilla oil is specifically beneficial to healing skin conditions and inflammation to yield resilient and good colored skin. One would have a reasonable expectation of success in substituting a safe plant oil such as perilla oil for a known allergen such as groundnut oil to obtain the composition of '109 in view of '834.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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